510(k) Summary

Date Prepared: 5-14-13

MAY 1 5 2013

Name of Sponsor:	NUTEK Orthopaedics, Inc. 641 SW 3rd Ave Ft. Lauderdale, FL 33315
510(k) Contact:	Peter Mincieli Chief Operating Officer Phone: (954) 818-9204 Fax: (954) 779-1900
Trade Name:	NBX® Non-Bridging External Fixator – Hand
Common Name:	External Fixation Devices – Bone Fixation Fasteners
Classification:	Class II per 21 CFR 888.3030; Multiple component metallic bone fixation Appliances and accessories
Device Product Code:	KTT – JEC

Substantially Equivalent Devices:

Small Bone Innovations	K051605
Howmedica Osteonics	K033476

Non-Clinical Performance Data	Equivalence to accepted methods of treatment for the products indications of use is covered in other sections of the application and based on non-clinical data. The performance data as defined in the study titled, Comparative Testing of External Fixation Devices in the following pages includes, Pin to Frame Coupling Pin Slip Tests, Pin to Frame Coupling Bend Test, Frame – Bone Axial Load Test, Construct Cantilever Bend Test
Device Description	The NBX® Non-Bridging Fixator – Hand is provided sterile. The fixator consists of the body with its proprietary locking mechanism and a multiple of pins.
Indications for Use:	The NBX® Non-Bridging External Fixator – HAND, is used for definitive external fixation, until healing. This device is used for the fixation of open or closed fractures, mal-union, and non-unions of the metacarpals and phalanges of the hand.
Material	316 Stainless Steel, ULTEM 1000 (Polyether Imide)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

NUTEK Orthopedics, Incorporated
% Mr. Peter Mincieli
Chief Operating Officer
301 Southwest 7th Street
Ft. Lauderdale, Florida 33315

Letter dated: May 15, 2013

Re: K122777
Trade/Device Name: NBX® – Non-Bridging External Fixator – Hand
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, JEC
Dated: April 17, 2013
Received: April 18, 2013

Dear Mr. Mincieli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122777

Device Name: NBX® Non-Bridging External Fixator – Hand

Indications for Use:

The NBX® Non-Bridging External Fixator – Hand, is used for definitive external fixation, until healing. This device is used for the fixation of open or closed fractures, mal-union, and non-union of the metacarpals and phalanges of the hand.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices